REMARKS

Entry of the foregoing amendment and reconsideration of the application, pursuant to and consistent with the Rules of Practice in Patent Cases, in light of the remarks which follow, is respectfully requested. The present RCE application is a continuation of Application No. 10/079,071, filed February 20, 2002. Claims 1-9, 12, 22, 26-30, and 32-34 have been amended and claims 10-11 have been deleted from the parent application, so that upon entry of the present amendment claims 1-9 and 12-34 will be pending.

In the parent application, claims 1-34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,356,951 to Yearn et al. ("Yearn") in view of WO 00/61703 to Blackwell et al. ("Blackwell"), DE 3502594 A1 to Michl et al. ("Michl"), U.S. Patent No. 4,503,169 to Randklev ("Randklev"), and U.S. Patent No. 4,668,712 to Hino et al. ("Hino"). The this rejection is traversed for at least the following reasons.

The present invention relates to a composition useful as a dental material containing a particulate composite filler having an average particle size of 20 to 50 μm and containing at most 10 wt.-% of particles with a size of < 10 μm. The present invention provides polymerizable compositions with low polymerization shrinkage, transparency and polishability. The compositions achieve these desired characteristics through the use of a novel filler based on a particulate composite material.

As described in the present specification, a suitable particulate composite material can be prepared, for example, by mixing an organic binder and filler, a polymerization initiator, curing, and then grinding the mixture (page 5, last paragraph). As is known in the art, during normal grinding of a composite material, a considerable amount of fine particulate material (i.e., having a particle size of < 10 μm) is formed (page 6, second paragraph). Example 1 and Figure 1 of the present specification show, for example, that grinding of such a composite material to an average particle size of 21 μm resulted in the formation of particles having a size of less than 10 μm in a proportion of about 40 percent.

Applicants have surprisingly found that removing this fine particulate material from the composite filler (i.e., by restricting the amount of particles having a grain size of less than 10 μm to 10 wt.-% or less), can reduce the degree of polymerization shrinkage of the composition. Examples 2 and 3 of the present invention, for example, show that the

polymerization shrinkage of a polymerizable composition was reduced from 1.9% to 1.6% by removing the fine particulate material.

Yearn do not disclose dental materials or fillers according to the composition of the present invention. Yearn teach the use of a filler having three components. One of these components, component (b-i), is a composite filler. However, contrary to the present invention, this composite filler includes substantial amounts of particles having a size of less than 10 μm. In the examples Yearn use composite materials having a mean particle diameter within the range of 8 μm (column 5, line 67) to 15 μm (column 5, lines 57 to 58), i.e. filler having a mean particles size which is below 20 μm. All materials used in the examples are obtained by curing and pulverizing a mixture of monomer and glass powder (column 5, lines 29 to 67). It was shown by the present inventors that common pulverization of composite materials results in the formation of a substantial amount of fine particulate material. In Example 1 of the present application it is shown that grinding of a composite material to an average grain size of 21 μm results in the formation of about 40% of particles having a size < 10 μm. Therefore, it is evident that the materials disclosed by Yearn must contain a significant portion of particles having a size of less than 10 μm.

Blackwell discloses polymerizable compositions having filler combinations with a defined size distribution and size relationship (page 3, last paragraph). According to Blackwell a composite paste containing ground glass particles with a particle size distribution of about 0.05 to 1 μm together with small amounts of siliceous filler with a particle size distribution between about 0.01 and 0.1 μm (page 4, lines 1 to 4) is mixed with an additional fraction of filler chosen such that the mean particle size of this additional filler is at least about 20 times the size of the largest filler in the paste (page 4, lines 15 to 17). Specifically disclosed on page 4 , lines 21-23 is an additional filler having a mean particle size of at least about 20 μm with no particles larger than 25 μm or smaller than 15 μm. The second filler does not render obvious the particulate composite material of the present invention as it would not have been obvious to substitute this second filler for the composite filler of Yearn.

It should be noted that Blackwell teaches the use of milled glass as the second filler component (page 5, lines 1. to 2). According to Example 2 the additional filler is made by milling glass frit with a particle size of 2 to 5 μm to obtain powder with a particle size ranging from about 1 μm to 1 mm and having a mean particle size of about 50 μm (paragraph

bridging pages 5 and 6). This powder is sieved to obtain Fraction A having a particle range between 100 to 250 μm and Fraction B having a particle size range of 48 to 85 μm (page 6, first paragraph). It is evident that the average particle size of both fractions is outside the claimed range of 20 to 50 μm of the composite filler.

Blackwell does not teach the use of composite materials as the additional filler component. Composite fillers are prepared by mixing organic binder, filler and polymerization initiator, curing and grinding the mixture (see page 5, last paragraph of the present application). Milled glass is not a composite filler.

Yearn teach curable compositions which contain both a composite filler (b-i) and glass powder (b-ii). Thus, if a skilled person had combined Yearn and Blackwell he would not have replaced the composite filler component (b-i) with the glass powder of Blackwell in order to obtain a material having two glass powder fractions, but he would instead have replaced the glass powder (b-ii) with the glass powder of Blackwell. As a result he would have obtained a material including composite filler (b-i), which has substantial amounts of fine particulate material as explained above, and the glass powder of Blackwell. If the skilled person, contrary to the teaching of Yearn had replaced composite filler (b-i) with the glass powder of Blackwell he would have obtained a material having two different glass powders but no composite filler as required by the present invention. Therefore, a combination of the teachings of Yearn and Blackwell would not render the present invention obvious.

The present invention relates to polymerizable compositions with low polymerization shrinkage, transparency and polishability. It is an object of the present invention to provide dental materials with reduced polymerization shrinkage without adversely affecting the other properties of the materials. This object is achieved by dental materials having a composite filler including an average particle size of 20 to 50 μm and containing at most 10 wt.-% particles with a size of < 10 μm.

It was surprisingly found by the present inventors that the polymerization shrinkage of polymerizable compositions can be reduced using a composite filler with a restricted amount of particles having a grain size of less than 10 μm. The inventors demonstrated that by removing fine particulate material from composite filler the polymerization shrinkage could be reduced from 1.9% to 1.6% (compare Examples 2 and 3 of the present application).

The composition of Example 3 of the present invention resembles the compositions of Yearn in that it contains composite filler having fine particulate material which was not removed. It follows that the polymerization shrinkage of the claimed materials of the present invention is also improved with regard to the teachings of Yearn.

If a skilled person had added coarse material according to Blackwell to the materials of Yearn he would not have achieved compositions for use in dental material according to the present invention. According to the present invention a composition including 82% filler (page 17, lines 1 to 9; 2.5 wt.-% of 12.5 wt. -% layered silicate dispersed in monomer mixture corresponds to 0.3% solid materials in the final composite) shows a shrinkage upon polymerization of 1.6% (page 16, line 3). According to the table at page 14 of Blackwell, 86% filler is needed to achieve the same volume shrinkage of 1.6% (composition number 3). Thus, a significantly higher amount of filler is needed in accordance with the teachings of Blackwell.

According to this table, 86% of filler results in a volume shrinkage of 1.6%, 87% filler of 1.5% and 88% filler of 1.4%, respectively. Thus, raising the amount of filler by 1% reduces the shrinkage by about 0.1%. It can thus be estimated that a composition including 82% of filler as in Example 2 of the present application will have a volume shrinkage of about 1.9 to 2.0%. Thus, the polymerization shrinkage of the compositions according to Blackwell are comparable to the shrinkage of the material which has been used as the comparative material in Example 3 of the present application, i.e., it is significantly higher than the shrinkage of materials including the filler of the present invention. Consequently, the addition of coarse filling material as suggested by Blackwell does not result in the same improvement as the present invention.

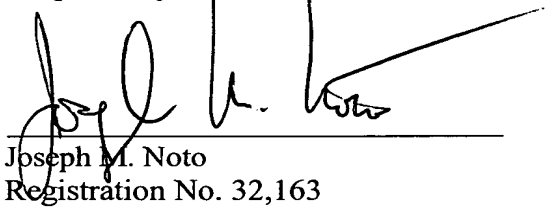
Moreover, materials other than the particulate composite filler of the present invention may contain additional filler having a particle size of <10 μm. In fact, such fillers are used in the examples of the present application. The materials of the present invention include a particulate composite filler as defined above as an important component. As is evident from the prior art discussed in the introductory section of the application, dental materials having only inorganic filler were not satisfactory. Moreover, as has been discussed above, the use of composite filler according to the prior art is also not satisfactory because it results in a high polymerization shrinkage. In addition, the fine particulate material contained in this prior art composite filler significantly raises the viscosity of the materials which makes

it difficult if not impossible to incorporate further fillers into the materials. It has been found by the present inventors that these disadvantages can be overcome by removing the fine particulate material from the composite filler. By doing this, other fillers, including fillers having a particle size of <10 μm, can be incorporated into the materials which allows further improvements of these compositions.

Accordingly, even if one were to combine the teachings of Yearn and Blackwell, the claimed invention is not achieved. The other secondary references cited by the Office, are said to disclose various dependent features of applicants' claims, and none of the references teaches, suggests, or recognizes the benefit to be obtained by reducing the proportion of fine particulate material in the composite filler. As none of the cited art, alone, or in combination, discloses the claimed invention, withdrawal of the record rejection is respectfully requested.

In view of all of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,



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